INFORMATION TECHNOLOGY INDUSTRY COUNCIL

July 6, 1999

Dockets Management Branch (HFA-305) 5362 '99 JUL -7 A11:51
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Proposed FDA Amendment to Performance Standard for Laser Products

Dear Sir/Madam:

The Information Technology Industry Council (ITI) appreciates this opportunity to comment on the Food and Drug Administration's (FDA) March 24, 1999 Proposed Rule to amend the performance standard for laser products. (64 Fed. Reg. 14180). ITI represents the leading U.S. providers of information technology products and services. Its members had worldwide revenues of $420.2 billion in 1997. They employ 1.2 million people in the United States.

FDA's proposal is based on the suppliers declaration of conformity (SDoC). ITI welcomes this approach. Under the SDoC, manufacturers assure regulators and customers that their products conform with all relevant national and international standards. SDoC reduces the cost and time caused by unnecessary duplicative testing and review prior to placing products on the market. Further, SDoC enables governments to better utilize their limited resources by focusing enforcement actions toward truly bad actors.

FDA's responsibility is not only to participate in the development of international standards but to demonstrate leadership and exert influence. ITI supports harmonization with IEC (International Electrotechnical Commission) standards whenever possible. Use of international standards facilitates international trade.

FDA is demonstrating leadership in this instance by not supporting the entire IEC Standard 825-1. FDA's decision to eliminate light emitting diodes (LEDs) from this proposed rulemaking will reduce the regulatory burden on affected manufacturers and improve the effectiveness of FDA's regulation of laser products. The present IEC standard for LEDs fails to allow for realistic factors of risk likely in the use of laser products. More IEC work must be done on this part of the standard. Because FDA is using a subset of the international standard and not creating any unique U.S. requirements, any product that complies with the international standard will meet the U.S. requirement. Therefore, this approach still facilitates international trade

Thank you for this opportunity to comment.

Sincerely,

Rhett Dawson
President

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